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The effect of bracket ligation on the periodontal status of adolescents undergoing orthodontic treatment. A systematic review and meta-analysis

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Short Title: Periodontal status of orthodontic patients. A meta-analysis

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Abstract

Introduction/Objectives: This systematic review aimed to critically appraise the evidence regarding the effect of bracket ligation type on the periodontal conditions of adolescents undergoing orthodontic treatment.

Data: Search terms included randomized controlled trial (RCTs), controlled clinical trials, ligation, bracket, periodontal, inflammation. Risk of bias assessment was made using the Cochrane risk of bias tool and the quality of evidence was assessed with GRADE.

Sources: Electronic Database search of published and unpublished literature was performed without language restriction in May 25, 2016 (MEDLINE via Pubmed, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Clinical Trials.gov and National Research Register).

Study Selection: Of 140 articles initially retrieved, 8 were eligible for inclusion in the systematic review, while 4 RCTs with unclear risk of bias were included in the quantitative synthesis, all comparing self-ligating to conventional steel ligated brackets. Random effects meta-analyses were implemented. At 4 to 6 weeks after bracket placement there was no evidence to support the use of either type of bracket for achieving improved plaque- (PI) and gingival index (GI). At 3 to 6 months, there was scarce evidence of greater PI increase for conventional brackets. GI and pocket depth pooled estimates did not reveal significant differences between the two systems. The quality of the evidence was moderate according to GRADE for all outcomes.

Conclusions: Overall, non-significant differences on the periodontal status of adolescents undergoing orthodontic treatment with either conventional or self-ligating brackets were detected.

Clinical Significance

The periodontal status of adolescents undergoing orthodontic treatment is of considerable importance. The synthesis of the available evidence on oral hygiene related factors will provide insights to best clinical practice during the course of orthodontic treatment.

Introduction

Despite its universal use and recent technical advancements, orthodontic treatment with bonded braces remains an impediment to an adequate oral hygiene, providing niches for food residues and bacteria [1-9]. Negative effects on dental hard tissue [10-16] as well as on the periodontium [1, 7, 15, 17-25] owing to orthodontic bands and brackets have been described, and several investigations showed that the presence of plaque at the gingival margin is the most important factor in the development of periodontal diseases [18, 26-28]. Several reports have highlighted the fact that orthodontic brackets are not only associated with noticeable periodontal adjustments, but that the method of archwire ligation onto fixed braces itself has an apparent influence on bacteria accumulation and periodontal status [2, 5, 9, 29].

In conventional edgewise brackets (CBs) systems, the archwire is ligated either with elastomeric rings or steel ligatures to the brackets. According to a number of studies an increase in biofilm accumulation has been reposted in patients with elastomeric ligatures [2, 5, 29-31].

Self-ligating brackets (SLBs), which entrap the archwire with an inbuilt component and do not necessitate further elastomeric rings or steel ligatures, were first introduced by Stolzenberg in the early 1930s [32]. Whilst SLBs were hardly used in the past, an increasing number of orthodontists have come to use them in recent years. Compared to 8.7% of American orthodontists who bonded SLBs in 2002, as many as 42% did so in 2008 [33, 34]. This increase can probably be explained by the fact that various newly developed systems entered the market in the past years, claiming advantages over CBs [35-37]. Indeed, many studies have been published in which the performance of SLBs and CBs have been compared, in various terms, such as friction, sliding mechanics and anchorage, number of appointments, treatment time, chair time, chair assistance, ergonomics, infection control, comfort for the patient, and oral hygiene [2, 36, 38-41]. Most of these studies have been analysed within the framework of systematic reviews, and while certain differences between SLBs over CBs

could be discerned through individual trial reports, the synthesis of most studies confirm the apparent equivalency of the bracket systems [42, 43].

The influence of the ligating method (SLBs over CBs) on periodontal health has also been investigated in several randomized controlled trials and other study designs [44-51], yet these investigations have never been pooled in a systematic way. As mentioned above, negative effects on the periodontium remain an unsolved problem in fixed orthodontic therapy, and any substantiated impact of the ligation method on periodontal health through a systematic review would be of high clinical relevance.

The aim of this study was therefore to systematically review the available literature on the effects of different ligation methods on periodontal health in adolescent orthodontic patients with fixed braces, while differentiating within CBs the type of ligature (steel ligature and elastomeric ligature). To assess periodontal health, the reported impact of SLBs and CBs on plaque index (PI), gingival index (GI) and probing depth (PD) was evaluated, respectively.

Material and Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses [52, 53] were followed for reporting of this systematic review. The review was not registered and no protocol was developed.

2.1 Eligibility Criteria

The following selection criteria were applied for this systematic review:

- Study design: Randomized Controlled Trials (RCTs) or Controlled Clinical Trials (CCTs) with more than 10 patients per group were considered.
- Participants: Adolescent patients or permanent dentition children wearing fixed orthodontic appliances.
- Interventions: Any type of ligation used with fixed appliances, either self-ligating or any type of conventional brackets with either elastomeric or stainless steel (ss) ligatures.

- Outcome measures: Changes in periodontal or gingival inflammation indices recorded throughout orthodontic treatment course. These included but were not confined to: Plaque Index (PI), Gingival Index (GI), Bleeding on Probing (BoP), Pocket Depth (PD).
- Exclusion Criteria: Studies involving patients with systematic or other diseases undergoing orthodontic treatment and studies involving adult patients (ie. >18 years of age).

2.2 Search Strategy

Electronic search within the following databases was undertaken in May 25, 2016, while no language restrictions were applied: Medline via Pubmed, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL). Moreover, unpublished literature was searched in ClinicalTrials.gov (www.clinicaltrials.gov) and the National Research Register (www.controlled-trials.com), using the terms «orthodontic» AND «periodontal». Hand searching of the reference lists of the retrieved full text articles was also conducted. Authors of original studies were contacted for data clarification where needed. Full search strategy employed in Medline via Pubmed is presented in Appendix 1.

Eligibility assessment, data extraction and Risk of Bias (RoB) assessment was implemented independently and in duplicate by two reviewers (SA and DK), while disagreements were resolved through discussion and after consultation with a third author (TE).

2.3 Data Extraction

Data extraction was performed on standardised piloted forms by two independently working reviewers (SA and DK) who were not blinded to author identity and study origin. Titles and abstracts were examined first followed by full text screening of the potential for inclusion articles. Information was obtained from each included study on study design, observation period and methods, participants, interventions, comparators and outcomes.

2.4 Risk of bias within studies

Risk of bias in individual studies was assessed according to the Cochrane Risk of Bias tool [54] for both RCTs and CCTs. In particular, the following domains were considered: 1. random sequence generation, 2. allocation concealment, 3. blinding of participants and/ or personnel involved in the study, 4. blinding of assessors, 5. incomplete outcome data reporting, 6. selective reporting of outcomes, 7. other sources of bias. An overall assessment of the risk of bias was made for each included study (high, unclear, low). Trials with at least 1 item designated to be at high risk of bias were regarded as having an overall high risk of bias. Trials with unclear risk of bias for one or more key domains were considered to be at unclear risk of bias and trials with low risk of bias in all domains were rated as low risk of bias. By convention it was regarded that CCTs were to be rated as of high risk of bias for the first two domains pertaining to the risk for selection bias.

2.5 Summary Measures and Data Synthesis

Clinical heterogeneity of included studies was assessed through the examination of individual trial settings, eligibility criteria, ligation methods used and data collection methods. Statistical heterogeneity was examined through visual inspection of the confidence intervals (CIs) for the estimated treatment effects on forest plots. Also, a chi-square test was applied to assess heterogeneity; a p-value below the level of 10% ($p<0.1$) was considered indicative of significant heterogeneity [55]. I^2 test for homogeneity was also undertaken to quantify the extent of heterogeneity.

Only studies at unclear or low risk of bias overall were included in meta-analyses, therefore only RCTs were deemed eligible for inclusion. Random effects meta-analyses were conducted as they were considered more appropriate to better approximate expected variations in trial settings. Treatment effects were calculated through pooled weighted mean differences (WMD) in periodontal/gingival index changes along with associated 95% Confidence Intervals (95% CIs) and Prediction Intervals where applicable (at least 3 trials needed). As a number of included studies were designed as split-mouth, the mean differences for those were calculated between quadrants and the standard deviation of the difference was approximated by the formula:

$$SD_{diff} = \sqrt{sd_1^2 + sd_2^2 - 2rsd_1sd_2}$$

where sd_1 and sd_2 indicate the standard deviations in quadrants and r the correlation coefficient between quadrants. The correlation coefficient was set at r=0.5 for split mouth studies and r=0 for parallel designs [56].

2.6 Risk of bias across studies

If more than 10 studies were included in meta-analysis, publication bias was to be explored through standard funnel plots [57].

2.7 Additional Analyses

Sensitivity analyses were pre-determined to explore and isolate the effect of studies with unclear risk of bias on the overall treatment effect if both low and unclear risk of bias studies were included.

All analyses were undertaken in Stata version 14.1 software (StataCorp, College Station, Texas, USA) using the command "metan".

2.8 Quality of the evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) were implemented to assess the overall quality of evidence as formulated by the interventions and the outcomes under study [58, 59]. According to GRADE the overall body of evidence is rated as high, moderate, low and very low. High quality of evidence means that further research is very unlikely to change our confidence in the estimated effect. Moderate: further research is likely to have an important impact on our confidence in the estimated effect and may change the estimate; Low: further research is very likely to have an important impact on our confidence in the estimated effect and is likely to change the estimate; very low: any estimated effect is very uncertain. Assessment is based on the following: risk of bias, inconsistency, indirectness, imprecision and publication bias. For the first 4 domains the quality of evidence may be downgraded on the basis of either ‘serious’ or

'very serious' risks, whereas the presence of publication bias may either be suspected or undetected (2 levels).

3. Results

3.1 Study selection and characteristics

One hundred and forty studies were initially identified. After duplicate exclusion and abstract screening, 14 studies were left for full text evaluation. Finally, 8 studies [44-51] were included in the qualitative synthesis, 4 of which [45, 46, 48, 49] were appropriate for data analysis (Figure 1). Of the 8 studies, all except one [51] were regarded as RCTs, while one study [49] was a 3-arm parallel and included an untreated control group. The design of the studies was parallel-group in 5 studies [44, 46, 47, 49, 51] and split-mouth in three [45, 48, 50]. All except one [50] involved intervention groups comprising of self-ligating and conventional brackets. Specifically, Akgun et al. [50] compared different types of elastomeric ligatures in conventional bracket systems, while Pandis et al. [51] and Nalçacı et al. [47] used elastomeric ligatures in their conventional brackets group in comparison to self-ligating brackets. All remaining studies [44-46, 48, 49] directly compared self-ligating to steel ligated conventional brackets (Tables 1 and 2).

The potential for data synthesis in meta-analyses was mainly based on individual study characteristics, pertaining to outcome structure and time-related outcome evaluation as well as on the inherent risk of bias and quality evaluation of the studies.

3.2 Risk of bias within studies

Details on the reporting of randomization and allocation concealment strategies were insufficient in all of the included studies. A similar trend was detected also for items pertaining to blinding/masking of the personnel involved or the outcome assessor. In this case it was acknowledged that blinding of the investigators or the patients as well as the clinician who was responsible for data recording was not possible due to the nature of the interventions. However, only Kaygisiz et al.[49] reported the involvement of an independent periodontist who was responsible for measuring the

periodontal/gingival indices. Four studies [47-49, 51] had a low risk of attrition bias as they clearly identified the losses to follow-up or withdrawals and/or reported sufficient details to allow for evaluation of the missingness mechanism. Lastly, selective reporting was rated as low risk of bias in most studies since sufficient details were included to allow for the assessment and pre-determination of study outcomes [45-49, 51]; nevertheless none of the included studies reported any pre-registration of a trial protocol (Figures 2 and 3).

3.3 Effects of Interventions, meta-analyses and additional analyses

Tables 3-4 present the mean changes in periodontal indices for the RCTs included in the meta-analyses. Plaque Index (PI) and Gingival Index (GI) mean changes per group are presented for the initial phase of the treatment (4-6 weeks from baseline), while PI, GI and Pocket Depth (PD) changes are shown additionally at 3 to 6 months of treatment course.

Minor reduction in the GI scores was noted at 4 to 6 weeks, both for self-ligating and for conventional bracket systems. This was also detected for PI scores by one [45] of the two contributing studies (Table 3). Considering the results at 3 to 6 months for the PI and GI mean changes, there was disagreement among the relevant studies [45, 46, 48]. According to de Almeida Cardoso et al. [45], slight reduction for PI and GI was evident for both SLB and CB, yet this was not substantiated by the other studies (Table 4). During the same time interval, a slight increase (in milimetres) was detected for both bracket systems regarding PD measurements (Table 4).

Random effects meta-analyses were undertaken based on the assumption that different mean differences in the change of periodontal outcomes prevailed in different settings and populations. The calculated effect sizes present the average effect.

Considering short term effects (within 4 to 6 weeks after bracket placement), there is no evidence to support the use of one type of bracket over the other for achieving improved periodontal status. For Plaque Index, the pooled weighted mean difference (WMD) in score change between conventional and self-ligating bracket systems was -0.09 (95% CIs: -0.36, 0.18; p=0.53). I^2 test for homogeneity confirmed meta-analysis for this outcome was reasonable (I^2=0.0%, chi-squared test: p= 0.93; Figure

4). Respectively, for the Gingival Index (GI) the pooled WMD was -0.02 with associated 95% CIs: -0.22, 0.19 (p=0.88) and I^2= 0.0% (chi-squared test: p= 0.94; Figure 5).

At 3 to 6 months on treatment course, there was very scarce evidence to support less PI increase with the use of self-ligated brackets (WMD= 0.14; 95% CIs: 0.0, 0.28; p=0.05) and related I^2= 0.0% (chi-squared: p=0.37). However, the Prediction Interval indicates that the true effect is likely to range between -0.76 to 1.03 (τ^2=0.00). As the Prediction Interval is wider and includes the value of 0 (null effect), this may indicate that under certain trial settings no difference is to be expected in mean PI changes from baseline to 3-6 months between conventional and self-ligating brackets (Figure 6).

GI changes at 3 to 6 months did not reveal significant differences between the two intervention groups (Conventional vs Self-ligating: WMD= 0.06; 95% CIs: -0.24, 0.36; p=0.70). Again, no evidence of heterogeneity could be detected (I^2=0.0%; chi-squared: p=0.38; Figure 7). Results regarding Pocket Depth measurements could only be pooled for the 3-6 months duration period. WMD for conventional as compared to self-ligating brackets was 0.01 (95% CIs: -0.12, 0.14; p=0.86; Figure 8). Statistically, heterogeneity appeared increased, but remained on an acceptable level (I^2= 24%; chi-squared: p=0.25).

No sensitivity or other additional analyses were undertaken as only unclear risk of bias trials were included in the syntheses.

3.4 Risk of Bias across studies

Exploring for publication bias either statistically or graphically was not undertaken as no more than 3 studies were included in an individual meta-analysis.

3.5 Quality of the Evidence

The assessment of the quality of evidence on periodontal status of orthodontic patients treated with either conventional or self-ligating brackets revealed that the level of the existing evidence was moderate for all assessed outcomes (Tables 5 and 6). These findings suggest that further research is likely to have an important impact on our confidence in the effect estimate and may change the estimate.

4. Discussion

Increased plaque accumulation is a known and serious problem during the course of a fixed orthodontic therapy [44, 46-51]. Some of the risk factors which may pose a positive effect on plaque accumulation during orthodontic treatment, such as oral hygiene, have been thoroughly reviewed by previous studies [2, 12, 28, 60-65]. To a far lesser extent the influence of ligation method and bracket type has been evaluated. In response to the paucity of the available evidence, this systematic review aimed to identify the effects of different ligation methods on the periodontal health of adolescent orthodontic patients with fixed appliances.

Pertinent literature indicates that adolescent patients tend to accumulate significantly more plaque than adults [28, 66], while the influence of gender seems rather limited [67]. Hence, the present systematic review focused on studies performed with adolescent participants of both sexes. Four RCTs with unclear risk of bias were included in the meta-analyses.

4.1 Plaque Index and Gingiva Index (PI and GI) changes at 4 to 6 weeks

Of all studies included on short-term changes of PI and GI in the systematic review [45, 47, 49, 50], only Nalçaci et al.[47] attested that PI and GI were significantly lower in SLBs than in CBs after 5 weeks. The difference revealed in just one single study should, however, be interpreted with caution, as this could be attributed to unaccounted potential confounders causing spurious associations. Certain known and unknown parameters are evidently difficult to control without clear and sound randomization procedures, while differences in the management of oral hygiene, changes in dietary habits or variations in bonding procedures may bear a considerable impact on the observed results. It is interesting to note that GI scores at 4-6 weeks were slightly decreased in two studies [45, 49]. This could be the product of the observation period chosen, which could be challenged as too short to allow for the establishment of any real biological change, and which might only reflect the result of patients' initial high ambitions in oral hygiene. Considering the consolidated results for the short

term effect, there seems to be no evidence to support any claimed superiority of SLBs over CBs concerning periodontal health at 4-6 weeks.

4.2 Plaque Index (PI), GI Index (GI) and Pocket Depth (PD) changes at 3 to 6 months

Long-term periodontal changes were appraised based on five trials [44-46, 48, 51]. In contrast to the short-term results presented by Nalçaci et al. [47], Pandis et al. [51] did not find any long-term significant differences of any periodontal indices when comparing SLBs and CBs ligated with elastomeric rings. Again, the divergent results might be grounded in baseline confounders, most probably the different observation periods, study design and population, units of assessment, statistical analyses and type of SLBs used. Pandis et al. [51] assessed only the mandibular anterior teeth. Since these teeth have a shorter inter-bracket distance and reduced crown widths, they may be prone to increased plaque accumulation. Although the disparity of the studies does not allow any conclusive remarks, this underscores the need to further question the generalizability of any results retrieved from selected dentition segments.

Three studies evaluating the long-term PI changes related to SLBs and CBs ligated with steel ligatures were included in the meta-analyses [45, 46, 48]. In contrast to short-term PI changes, a non-significant tendency in long-term PI changes could be observed, with results somewhat more favorable for the SLB group. The outcome of the meta-analysis on GI discloses a less pronounced trend, but similar to PI in favor of SLBs. Atik et al. [46], who reported a higher PI increase in the CB group in the long-term, found GI to be decreased in with the very same patient group. Conversely, the group with the higher PI score in the investigation of de Almeida Cardoso et al. [45] had the lower GI score. Apart of the manifestly missing causative link, the rather small sample size of the studies, the non consistent study designs and statistical analyses, and the unclear risk of bias render further long-term RCTs clearly indispensable to confirm the trend seen at 3-6 months in favor of the SLBs. PD changes while using SLBs and CBs ligated with elastomeric or steel ligatures, was extracted from four studies [44, 46, 48, 51]. Conflicting opinions exist concerning any potential influence of

fixed braces treatment on PD. In the past, some have disputed any significant increase in PD after bracket bonding [3, 20, 23]. This opinion is supported by three of the studies included in this systematic review [44, 46, 51]. On the other hand, an effect of orthodontic brackets on PD has been observed in one report [30] and has been reaffirmed in one trial, included in this systematic review [48]. However, any report on PD increase during orthodontic treatment has to be read with due prudence, since significant increase in PD might be attributed to gingiva hypertrophy rather than attachment loss. However, none of these trials found significant differences in PD changes for both SLBs and CBs. The same outcome was shown in the meta-analysis, which included two trials with unclear risk of bias [46, 48].

The quality of the evidence from the meta-analyses was moderate and could be regarded as satisfying, considering that 79% of the prevailing meta-analyses in orthodontic literature report low or very low quality of evidence [68]. Nonetheless, various concerns admittedly limit the value of the present meta-analyses: No meta-analysis incorporates outcomes from more than three studies and all are based on few participants limiting the precision of the retrieved estimate; they involve a rather short observation period and are all of unclear risk of bias. Inclusion of split-mouth design might possibly introduce bias due to cross-contamination within the same individual especially with regard to plaque index which might be affected while brushing. On the other hand, this type of design is particularly effective in eliminating selection bias due to known or unknown factors when improper randomization procedures are followed. It should be acknowledged that none of the included in the meta-analyses four trials compared SLBs versus CBs ligated with elastomeric rings. Yet elastomeric rings are evidently much more in use than steel ligatures, and additional original studies and meta-analyses comparing SLBs and CBs ligated with elastomeric rings would be a welcome addition to the orthodontic literature.

5. Conclusions

Based on the systematically analyzed literature, there is no evidence to support the claim that SLBs have relevant clinical advantages over CBs with regard to periodontal health in adolescents with bonded brackets. Effective brushing should be the primary concern of young patients while undergoing orthodontic treatment to maintain high levels of oral hygiene, irrespective of the bracket system used. This review further demonstrated that 4-6 weeks into orthodontic treatment seems too short an observational period to allow for conclusive remarks on periodontal health, and that a discrimination within conventional brackets would be advisable for elastomeric or steel wire ligatures to be assessed. Finally, most of the studies included in this systematic review displayed methodological drawbacks, while additional high-quality randomized controlled investigations are deemed necessary to confirm the findings that SLBs do not have advantages over CBs regarding periodontal health.

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Appendix 1.

MEDLINE search

Limits: ‘Humans’, no language restriction applied

Publication date: no restriction

Search Builder: ‘All Fields’

Four consecutive searches combined with "AND" Boolean operator, using “OR” between MeSH terms or keywords:

1. randomized controlled trial
2. randomised controlled trial
3. randomized clinical trial
4. randomised clinical trial
5. controlled clinical trial
6. clinical trial
7. prospective clinical trial
8. prospective controlled trial
9. prospective cohort
10. cohort
11. 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10
12. ligating
13. ligation
14. ligat*
15. ligature
16. self-ligation
17. self-ligating
18. self-ligat*
19. conventional
20. steel
21. elastomeric
22. 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21
23. bracket
24. braces
25. brace
26. brackets
27. appliance
28. appliance*
29. 23 OR 24 OR 25 OR 26 OR 27 OR 28
30. periodontal
31. periodont*
32. oral hygiene
33. hygiene
34. gingival
35. gingiv*
36. plaque
37. bleeding
38. inflammation

39. inflammat*
40. 30 OR 31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38 OR 39
41. 11 AND 22 AND 29 AND 40

Legends for illustrations

Figure 1. PRISMA flow diagram of study selection

Figure 2. Risk of bias summary outlining judgement of risk of bias items for studies included in the quantitative synthesis

Figure 3. Risk of bias summary outlining judgement of risk of bias items for studies excluded from the quantitative synthesis

Figure 4. Random effects meta-analysis of change in Plaque Index (PI) for conventional and self-ligating brackets at 4 to 6 weeks

Figure 5. Random effects meta-analysis of change in Gingival Index (GI) for conventional and self-ligating brackets at 4 to 6 weeks

Figure 6. Random effects meta-analysis of change in Plaque Index (PI) for conventional and self-ligating brackets at 3 to 6 months

Figure 7. Random effects meta-analysis of change in Gingival Index (GI) for conventional and self-ligating brackets at 3 to 6 months

Figure 8. Random effects meta-analysis of change in Pocket Depth (PD) for conventional and self-ligating brackets at 3 to 6 months

Table 1. Study characteristics of included in the quantitative syntheses studies: Design, observation period, method of outcome assessment, interventions, and outcome measures

Study	Design	Observation Period/method	Participants	Interventions	Outcomes/Related Indices
Baka et al., 2013	RCT split mouth	Total 3 months: before trx, 1 week, 3 months *- full mouth*	20 patients: 20 male, mean age 14.2 ± 1.5 years (range 11.0-16.7 years)	• Self-ligating: 0,022 in-slot, Damon Q, Ormco, Orange, Calif • Conventional: Roth-equilibrium 2, 722-341; Dentaurum, Pforzheim,German, steel ligatures	• PI • BoP • PD
Atik et al., 2014	RCT parallel	Conventional: Total 15.3 months, before trx, 6 months, end of treatment Self-ligating: Total 13.3 months before trx, 6 months, end of treatment *- full mouth*	33 patients: 33 female, conventional group: mean age 14.5±1.2 years Self-ligating group: mean age 14.8±1.0 years	• Self-ligating: 0.022-inch Damon 3MX (Ormco/A Company, San Diegeo, Calif) • Conventional: 0.022-inch Roth bracket system (Forestadent, Pforzheim, Germany), steel ligatures	• GI • PI • PD
de Almeida Cardoso et al., 2015	RCT split mouth	Total 180 days; before trx, 1 month, 2 months, 6 months *- full mouth*	16 patients, age range 12 to 16 years	• Self-ligating: Prtia model (3M, Sao Jose Rio Preto, Sao Paulo, Barzil) with a slot locking mechanism made of nickel titanium • Conventional: Kirium model (Abzil-3M, Sao Jose Rio Preto, Sao Paulo, Brazi), steel ligatures	• PI • GI • CAL
Kaygisiz et al., 2015	RCT parallel	Total 8 weeks: one week before trx, immediately before trx, 1 week, 4 weeks, 8 weeks *- full mouth*	60 patients: 28 female, 32 male, age range 12 to 18 years	• Self-ligating: F1000, 0.022 inche, Leone SpA, Sesto Fiorention, Florence, Italy • Conventional: Avex MX, 0.022 inch, Opal Orthodontics, Soth Jordan, Utah, steel ligatures • Control: no trx	• PI • GI • PD • BoP

RCT: randomized controlled trial, trx: treatment, GI: gingival index, PI: plaque index, PD: pocket depth, BoP: bleeding on probing, CAL: clinical attachment level

Table 2. Study characteristics of excluded from quantitative syntheses studies: Design, observation period, method of outcome assessment, interventions, and outcome measures

Study	Design	Observation Period/method	Participants	Interventions	Outcomes/Related Indices
Pandis et al., 2008	CCT parallel	Average trx time: 18 months *- 6 anterior mandibular teeth*	100 patients: 36 male, 64 female, age range 12-17 years	• Self-ligating: In-Ovation-R, GAC International • Conventional: Micro arch; GAC International, Central Islip, NY, USA with elastomeric ligatures	• PI • GI • PD • CI
Pejda et al., 2013	RCT parallel	Total 3 months: before trx, 6 weeks, 12 weeks, 18 weeks *- full mouth*	38 patients: 13 male, 25 female, mean age: 14.6 ± 2.0 years	• Self-ligating: Damon 3MX, Ormco-Corporation, Glendora, Calif • Conventional: Sprint brackets, Roth System-Slot 0.018, Forestadent, stainless steel ligatures	• PD • GI
Nalçacı et al., 2014	RCT parallel	Total 5 weeks: before trx, 1 week, 5 weeks *- full mouth*	46 patients: 24 females, 22 males, SLB Group: mean age 14.48 ± 1,27, Conventional Group: mean age 13.30± 1.61 years	• Self-ligating: Damon Q, Ormco, Glendora, Calif • Conventional: Mini Taurus, Rocki Mountain Orthodontics, Denver, Col, elastomeric ligatures	• GI • PI • BoP
Akgun et al., 2014	RCT split mouth	Total 5 weeks; before trx, 1 week, 5 weeks *-2nd premolars*	13 patients: 10 girls, 3 boys, mean age 16.2 years	• Slide elastomeric ligatures • Conventional elastomeric ligatures	• GI • PI • BoP • PD

RCT: randomized controlled trial, CCT: controlled clinical trial, trx: treatment, GI: gingival index, PI: plaque index, PD: pocket depth, CI: Calcus Index, BoP: bleeding on probing

Table 3. Plaque Index (PI) and Gingival Index (GI) mean changes from baseline in the short term (4 to 6 weeks) for the included in the quantitative syntheses studies.

Study	**Interventions (number of patients)**	**Mean change (SD)**	
		Self-ligating	**Conventional**
		Plaque Index (PI)	
Kaygisiz et al., 2015	Self-ligating (20), Conventional (20)	0.36 (0.42)	0.27 (0.46)
de Almeida Cardoso et al., 2015	Self-ligating (16), Conventional (16)	-0.23 (1.15)	-0.21 (1.16)
		Gingival Index (GI)	
Kaygisiz et al., 2015	Self-ligating (20), Conventional (20)	-0.01 (0.33)	-0.03 (0.44)
de Almeida Cardoso et al., 2015	Self-ligating (16), Conventional (16)	-0.26 (0.92)	-0.26 (0.87)

negative sign (-) denotes decrease during time in the periodontal indices

Table 4. Plaque Index (PI), Gingival Index (GI) and Pocket Depth (PD) mean changes from baseline in the long run (3 to 6 months) for the included in the quantitative syntheses studies.

Study	**Interventions (number of patients)**	**Mean change (SD)**	
		Self-ligating	**Conventional**
		Plaque Index (PI)	
Baka et al., 2013	Self-ligating (20), Conventional (20)	1.16 (0.38)	1.37 (0.34)
Atik et al., 2014	Self-ligating (16), Conventional (17)	0.45 (0.37)	0.52 (0.40)
de Almeida Cardoso et al., 2015	Self-ligating (16), Conventional (16)	-0.51 (1.03)	-0.61 (1.00)
		Gingival Index (GI)	
Atik et al., 2014	Self-ligating (16), Conventional (17)	0.22 (0.60)	0.15 (0.60)
de Almeida Cardoso et al., 2015	Self-ligating (16), Conventional (16)	-0.4 (0.74)	-0.20 (0.95)
		Pocket Depth (PD)	
Baka et al., 2013	Self-ligating (20), Conventional (20)	0.72 (0.31)	0.68 (0.32)
Atik et al., 2014	Self-ligating (16), Conventional (17)	0.19 (0.33)	0.29 (0.25)

negative sign (-) denotes decrease with time in the periodontal indices

Table 5. Summary of Findings Table according to GRADE for 4 to 6 weeks. Number of Participants, effect estimates and quality of the evidence for Plaque Index (PI) and Gingival Index (GI).

Conventional compared to Self-ligating for periodontal status (indices)

Patient or population: Orthodontic Patients with fixed appliances
Settings: various
Intervention: Conventional
Comparison: Self-ligating

Outcomes*	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Self-ligating**	Corresponding risk **Conventional**				
Change in Plaque Index		The weighted mean change in plaque index in the intervention groups was **0.09 lower** (0.36 lower to 0.18 higher)		72 (2 studies)	⊕⊕⊕⊖ **moderate**[1]	
Change in Gingival Index		The weighted mean change in gingival index in the intervention groups was **0.02 lower** (0.22 lower to 0.19 higher)		65 (2 studies)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] unclear RoB for several domains

* please note that for the outcomes studied conventional brackets were regarded as Intervention group for the sake of conveniency

Table 6. Summary of Findings Table according to GRADE for 3 to 6 months. Number of Participants, effect estimates and quality of the evidence for Plaque Index (PI), Gingival Index (GI) and Pocket Depth (PD).

Conventional compared to Self-ligating brackets for periodontal status (indices)

Patient or population: Orthodontic Patients with fixed appliances
Settings: various
Intervention: Conventional
Comparison: Self-ligating

Outcomes*	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Self-ligating**	Corresponding risk **Conventional**				
Change in Plaque Index		The weighted mean change in plaque index in the intervention groups was **0.14 higher** (0 to 0.28 higher)		105 (3 studies)	⊕⊕⊕⊖ **moderate**[1]	
Change in Gingival Index		The weighted mean change in gingival index in the intervention groups was **0.06 higher** (0.24 lower to 0.36 higher)		65 (2 studies)	⊕⊕⊕⊖ **moderate**[1]	
Change in Pocket Depth		The weighted mean change in pocket depth in the intervention groups was **0.01 higher** (0.12 lower to 0.14 higher)		73 (2 studies)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] unclear RoB for several domains

* please note that for the outcomes studied conventional brackets were regarded as Intervention group for the sake of conveniency to demonstrate superiority. Positive values of estimates indicate greater index increase (this is negative for periodontal condition)

Figure 1. PRISMA flow diagram of study selection

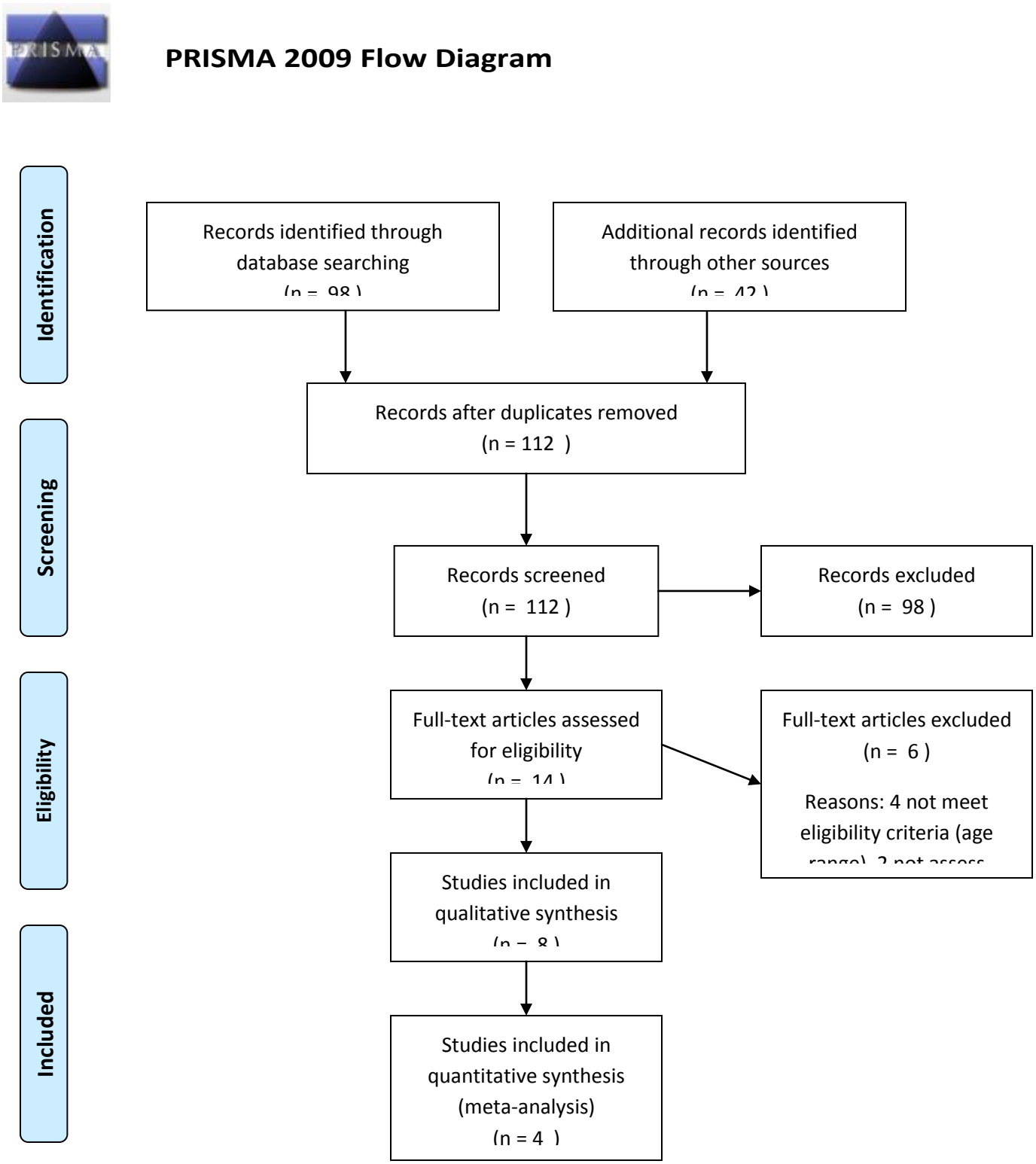

Figure 2. Risk of bias summary outlining judjement of risk of bias items for studies included in the quantitative synthesis

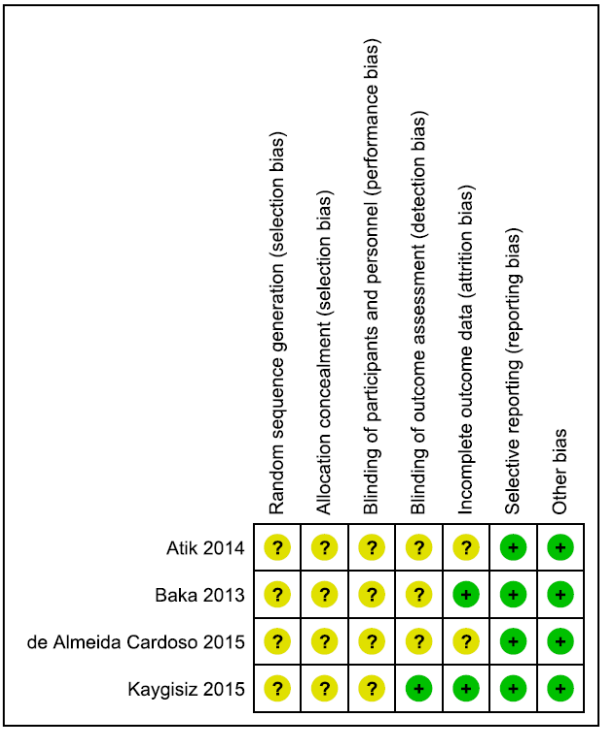

Figure 3. Risk of bias summary outlining judjement of risk of bias items for studies excluded from the quantitative synthesis

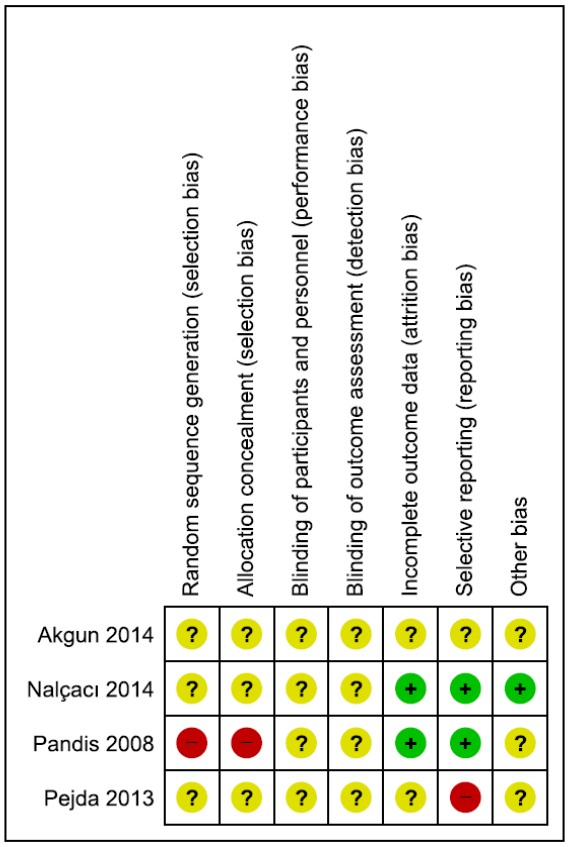

Figure 4. Random effects meta-analysis of change in Plaque Index (PI) for conventional and self-ligating brackets at 4 to 6 weeks

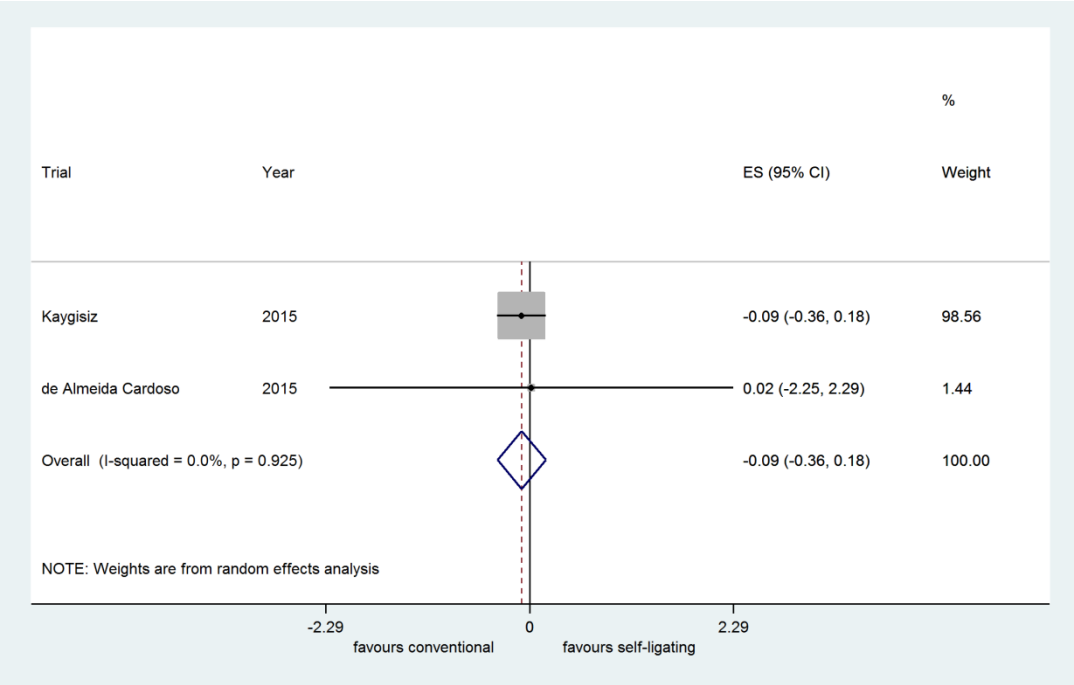

Figure 5. Random effects meta-analysis of change in Gingival Index (GI) for conventional and self-ligating brackets at 4 to 6 weeks

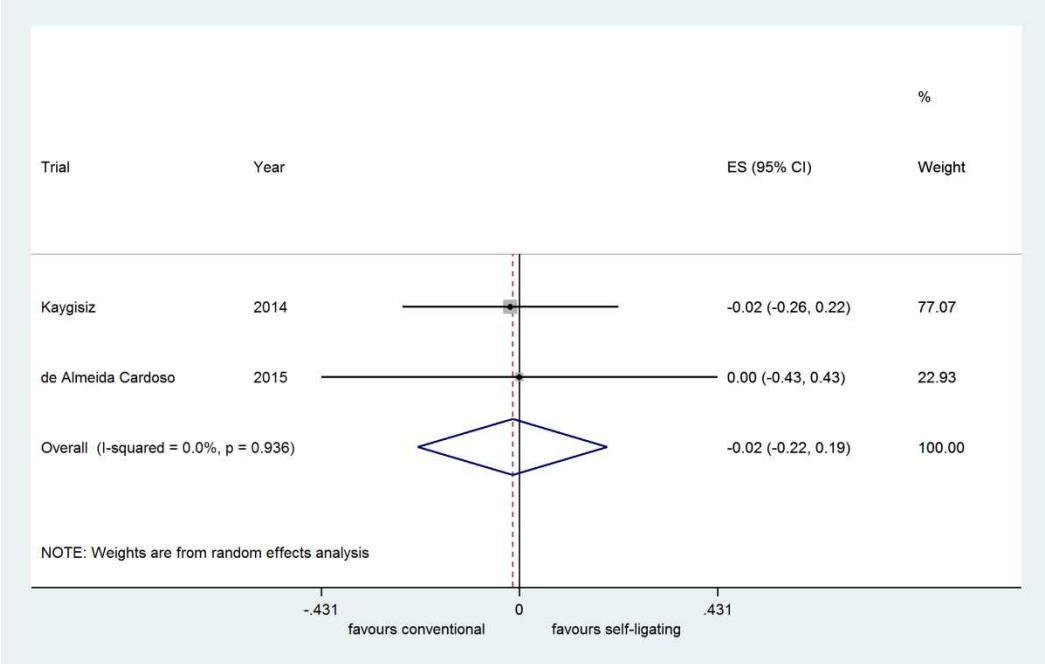

Figure 6. Random effects meta-analysis of change in Plaque Index (PI) for conventional and self-ligating brackets at 3 to 6 months

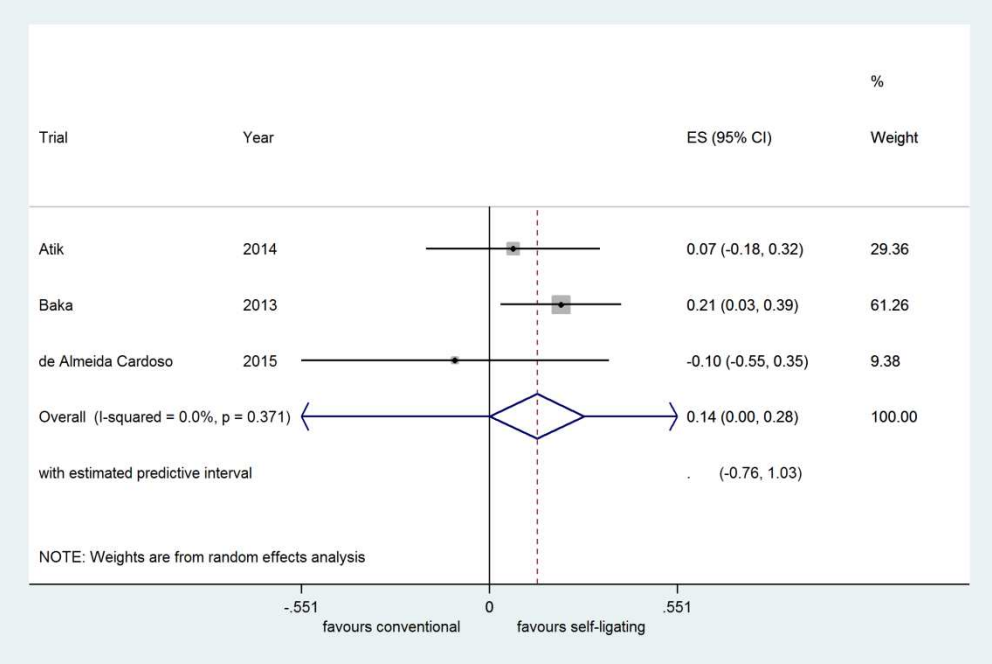

Figure 7. Random effects meta-analysis of change in Gingival Index (GI) for conventional and self-ligating brackets at 3 to 6 months

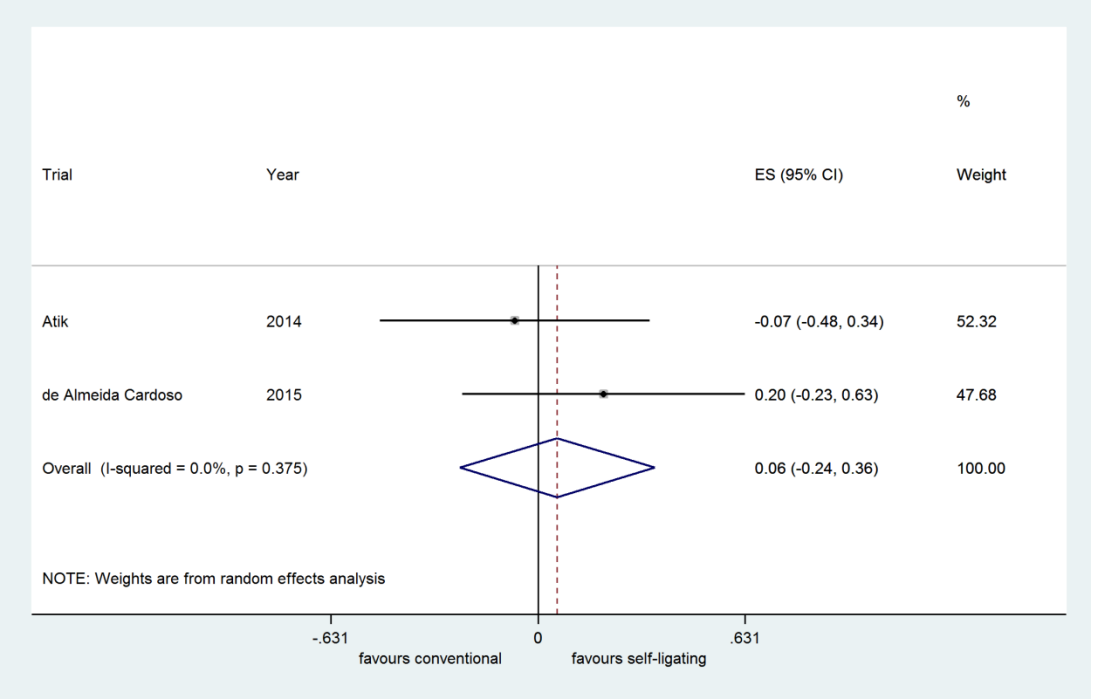

Figure 8. Random effects meta-analysis of change in Pocket Depth (PD) for conventional and self-ligating brackets at 3 to 6 months